4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Pediatric Ethics Subcommittee of the Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a subcommittee of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Subcommittee: Pediatric Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Subcommittee: To advise and make recommendations to the Pediatric Advisory Committee on pediatric ethical issues.

Date and Time: The meeting will be held on September 9, 2013, from 8 a.m. to 5:30 p.m. and September 10, 2013, from 8 a.m. to 3 p.m.

Location: Doubletree Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910, 301-589-5200 or visit the hotel's Web site at http://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-hotel-washington-dc-silver-spring-DCASSDT/index.html.

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993, 301-796-0885, email walter.ellenberg@fda.hhs.gov or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal

Register about last minute modifications that impact a previously announced subcommittee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 9 and 10, 2013, the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee will meet to discuss ethical issues in pediatric product development, including medical counter measures, focusing on the concepts of minimal risk, disorder or condition, and exposure of pediatric subjects to risks under 21 CFR 50.54.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the subcommittee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 9, 2013. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of

proposed participants, and an indication of the approximate time requested to make their presentation on or before August 30, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 3, 2013.

Persons attending FDA's subcommittee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at this meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg at 301-796-0885, email walter.ellenberg@fda.hhs.gov, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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